Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0469661	02/03/2021
Name of Provider or Supplier	**Street Address, City, State**	
Ssm Health St Anthony Healthplex El Reno	3333 Territory Lane, El Reno, OK	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The recertification survey was performed on 02/01,02,03/2021. The findings were reviewed with laboratory director, QA specialist, laboratory manager, laboratory lead, and regional laboratory director during an exit conference performed at the conclusion of the survey. The laboratory was found in compliance with standard-level deficiencies cited.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with the QA specialist, the laboratory failed to ensure attestation statements were signed by the laboratory director or designee for one of 21 events. Findings include: (1) On 02/01/2021, the surveyor reviewed 2019 and 2020 proficiency testing records with the following identified: (a) First 2020 Hematology/Coagulation Event - The attestation statement had not been signed by the laboratory director or designee. (2) The surveyor reviewed the records with the QA specialist. The QA specialist stated on 02/01/2021 at 12:51 pm the attestation statement had not been signed by the laboratory director as indicated above.

D3021	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(1) Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product. This STANDARD is not met as evidenced by: Based on a review of records and interview with the QA specialist, the laboratory failed to ensure an adequate alarm system was in place for the blood bank refrigerator for three of eight alarm checks. Findings include: (1) On 02/01/2021 at 11:45 am, the QA specialist stated to the surveyor the laboratory routinely maintained packed red blood cells in the blood bank refrigerator. The units were available for emergency patient transfusions (packed red blood cells must be stored at 1-6 degrees Centigrade-C); (2) On 02/02/2021, the surveyor asked the QA specialists how often the alarm checks were performed. The QA specialist stated on 02/02/2021 at 02:45 pm the alarm checks were performed on a quarterly basis; (3) The surveyor then reviewed the alarm check records for 2019 and 2020. It was identified that alarm checks were not performed as follows: (a) Between 07/29/2019 and 01/03/2020 (4) The surveyor reviewed the records with the QA specialist. The QA specialist stated on 02/02/2021 at 03:10 pm, the alarm checks had not been documented as performed as indicated above.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions and interview with the QA specialist, the laboratory failed to follow the manufacturer's instructions for implementing a coagulation reagent for one of one lot number; and failed to follow manufacturer's instructions for verifying flags obtained on the Hematology analyzer for 15 of 40 records . Findings include: IMPLEMENTING COAGULATION REAGENT (1) On 02/01/2021 at 11:40 am, the QA specialist stated to the surveyor the Stago STA Satellite analyzer was used to perform PT/INR (Prothrombin Time /International Normalized Ratio) testing (the INR was calculated using the PT reference interval mean) and D-Dimer testing; (2) On 02/02/2021, the surveyor reviewed the manufacturer's instructions for implementing new reagents, which stated: (a) "Normal Reference Ranges" (i) "The reference interval verification study may be performed using a minimum of 20 screened normal samples." (b) "8.4 Criteria for reference range "normal" donors:" (i) "Drug History" (aa) "Patients excluded if taking the following drugs: Birth control or estrogen containing products, Coumadin, Heparin (UFH, LMWH or heparinoid), Direct Thrombin Inhibitors, Antibiotics" (ii) "Conditions" (aa) "Patients excluded if they are pregnant or have any known immunologic diseases." (3) The surveyor reviewed the laboratory's implementation records for the current PT reagent (STA-Neoplastine CI PLUS lot# 256761 put into

	use on 01/01/2021) and identified the following: (a) For five female donors and three male donors there was no drug history and medical condition documentation to prove the samples were from normal patient donors. (4) The surveyor reviewed the findings with the QA specialist who stated on 02/02/2021 at 03:45 pm, the manufacturer's instructions had not been followed for the reagent lot change as indicated above. VERIFYING HEMATOLOGY FLAGS (1) On 02/01/2021 at 11:50 am, the QA specialist stated to the surveyor CBC (Complete Blood Count) testing was performed on the Sysmex XS 1000i analyzer; (2) On 02/02/2021 the surveyor reviewed the manufacturer's instructions for verifying automated differential flags obtained on the analyzer. The following were examples of flags, with the corresponding instructions: (a) Anisocytosis - "Verify RBC morphology on slide" (b) Atypical Lymphocyte? - "Perform manual differential" (c) Iron Deficiency - "Verify RBC morphology on slide" (d) Immature Gran? - "Perform manual differential" (e) Left Shift? - "Perform manual differential" (f) NRBC? - "Verify presence on slide, correct WBC count if necessary" (g) PLT Clumps? - "Verify on slide. Recollect sample if present." (h) Neutrophilia - "Review manual smear" (i) Thrombocytopenia - "Verify on slide" (3) On 02/02/2021, the surveyor randomly reviewed 40 patient records which contained flags from CBC testing performed between 12/01/2019 through 12/31/2019. For 15 of the records, there was no evidence the laboratory followed the manufacturer's instructions for verifying the flags. The findings for the 15 records were: (a) Record #1 - Testing was performed on 12/01/2019 at 11:12 am, with an Atypical Lymphocyte? flag obtained; (b) Record #2 - Testing was performed on 12/02/2019 at 06:17 pm, with an Atypical Lymphocyte? flag obtained; (c) Record #3 - Testing was performed on 12/03/2019 at 08:55 am, with an Iron Deficiency? flag obtained; (d) Record #4 - Testing was performed on 12/03/2019 at 10:13 am, with an Immature Gran?, Left Shift?, Thrombocytopenia, and 12/04/2019 at at PLT Clumps? flags obtained; (e) Record #5 - Testing was performed on 12/04/2019 at 10:02 am, with an Turbidity/HGB Interfr? flags obtained; (f) Record #6 - Testing was performed on 12 /04/2019 at 10:53 am, with a Neutrophilia and NRBC? flags obtained; (g) Record #7 - Testing was performed on 12/05/2019 at 04:48 pm, with an Anisocytosis and Iron Deficiency? flags obtained; (h) Record #8 - Testing was performed on 12/17/2019 at 11:10 am, with an Immature Gran? flag obtained; (i) Record #9 - Testing was performed on 12/17/2019 at 11:34 am, with a Neutrophilia flag obtained; (j) Record #10 - Testing was performed on 12/19/2019 at 05:59 pm, with an Neutrophilia flag obtained; (k) Record #11 - Testing was performed on 12/23/2019 at 07:03 am, with an Atypical Lymphocyte and Immature Gran? flags obtained; (l) Record #12 - Testing was performed on 12/23/2019 at 01:42 pm, with an Atypical Lymphocyte flag obtained; (m) Record #13 - Testing was performed on 12/26/2019 at 12:31 pm, with an Thrombocytopenia flag obtained; (n) Record #14 - Testing was performed on 12/31 /2019 at 04:12 am, with an Thrombocytopenia flag obtained; (o) Record #15 - Testing was performed on 12/31/2019 at 09:18 pm, with an Atypical Lymphocyte flag obtained; (4) On 02/03/2021, the surveyor reviewed the records with the QA specialist who stated on 02/03/2021 at 011:05 am there was no documentation to prove the flags obtained for the above 15 patients had been verified.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i) (B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii)

	Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's reportable ranges, and interview with the QA specialist, the laboratory failed to ensure the reportable ranges were utilized for two of two new test methods. Findings include: BNP CARTRIDGE (1) On 02/02 /2021 at 10:00 am, the QA specialist stated to the surveyor the laboratory performed BNP (B-type Natriuretic Peptide) testing using the BNP cartridge and iSTAT 1 analyzer. The system was available for patient testing on 08/30/2019; (2) The surveyor reviewed the performance specification records for the new test system and identified the laboratory had demonstrated the following reportable range: (a) BNP - 5.3 - 2173 ng/mL (3) The surveyor then reviewed the manufacturer's reportable ranges and the reportable ranges programmed into the laboratory's information system, which showed the laboratory was using the manufacturer's reportable ranges as follows: (a) BNP - 15 - 5000 ng/mL (4) The surveyor reviewed the findings with the QA specialist, who stated on 02/02/2021 at 02:30 pm, the laboratory was not using the reportable ranges that had been demonstrated by the laboratory as shown above. CHEM 8+ CARTRIDGE (1) On 02/02/2021 at 11:45 am, the QA specialist stated the laboratory performed BUN, Chloride, Creatinine, Glucose, ionized Calcium, Sodium, Potassium, and TCO2) testing using the iSTAT analyzer and Chem8+ cartridge. The system was available for patient testing on 07/21/2020; (2) The surveyor reviewed the performance specification records for the new test systems and identified the laboratory had demonstrated the following reportable ranges: (a) Chem 8+ (i) BUN - 5 - 134 mg/dL (ii) Chloride - 61 - 124 mmol/L (iii) Creatinine - 0.2 - 5.2 mg/dL (iv) Glucose - 27 - 599 mg/dL (vi) ionized Calcium - 0.36 - 2.31 mmol/L (vi) Potassium - 2.3 - 8.0 mmol/L (vii) Sodium - 100 - 178 mmol/L (viii) TCO2 - 14 - 39 mmol/L (3) The surveyor then reviewed the manufacturer's reportable ranges and the reportable ranges programmed into the laboratory's information system, which showed the laboratory was using the manufacturer's reportable ranges as follows: (a) Chem 8+ (i) BUN - 3 - 140 mg/dL (ii) Chloride - 65 - 140 mmol/L (iii) Creatinine - 0.2 - 20.0 mg /dL (iv) Glucose - 20 - 700 mg/dL (vi) ionized Calcium - 0.25 - 2.50 mmol/L (vi) Potassium - 2.0 - 9.0 mmol/L (vii) Sodium - 100 - 180 mmol/L (viii) TCO2 - 5 - 50 mmol/L (4) The surveyor reviewed the findings with the QA specialist, who stated on 02/02/2021 at 02:35 pm, the laboratory was not using the reportable ranges that had been demonstrated by the laboratory as shown above.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, written policies, and interview with the QA specialist,

	the laboratory failed to follow written quality control policies for three of four months. Findings include: (1) On 02/02/2021 at 10:00 am, the QA specialist stated to the surveyor: (a) The laboratory performed BNP (B-type Natriuretic Peptide) testing using the BNP cartridge and iSTAT 1 analyzer; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) The surveyor reviewed the IQCP that had been approved on 08/30/2019. The QCP (Quality Control Plan) portion of the IQCP required 2 levels of external QC (quality control) materials be tested once every 30 days; (3) The surveyor reviewed QC records for four months (December 2019, January 2020, February 2020, and March 2020) and identified the laboratory failed to follow the written QCP of performing QC testing every 30 days. QC testing had not been performed in January 2020, February 2020, and March 2020; (4) On 02 /03/2021 the surveyor reviewed the findings with the QA specialist who stated on 02 /03/2021 at 10:35 am, the laboratory had not performed QC testing as required by the QCP.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the QA specialist, the laboratory failed to perform two levels of control materials each day of patient testing using the CG8+ cartridge with the iSTAT analyzer for two of eight days of patient testing. Findings include: (1) On 02/01/2021 at 11:45 am, the QA specialist stated to the surveyor the laboratory performed Glucose, Ionized Calcium, Sodium, Potassium, pH, PCO2, and PO2 testing using the iSTAT analyzer and CG8 + cartridge; (2) On 02/02 /2021, the surveyor asked the QA specialist if an IQCP (Individualized Quality Control Plan) had been developed for the test system. The QA specialist stated on 02 /02/2021 at 10:00 am an IQCP had not been developed. Therefore, the surveyor determined two levels of QC (quality control) materials must be performed each day of patient testing; (3) The surveyor reviewed QC and patient testing records from 12 /29/2019 through 03/31/2020. The review showed that two levels of QC materials had not been performed two of eight days of patient testing reviewed as follows: (a) 02/23 /2020 - One level of QC material had been documented as performed (Level 1 tested on 02/23/2020 at 03:42 pm) (i) Patient tested on 02/23/2020 at 03:48 pm (b) 02/24 /2020 - Two levels of QC materials had not been documented as performed (i) Patient tested on 02/24/2020 at 03:47 pm (4) The surveyor reviewed the records with the QA specialist who stated on 02/02/2021 at 10:22 am two levels of QC materials had not been performed each day of patient testing.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

	This STANDARD is not met as evidenced by: Based on a review of records and interview with the QA specialist, the laboratory failed to make appropriate reference ranges available. Findings include: (1) On 02/01 /2021 at 11:40 am, the QA specialist stated to the surveyor the Stago STA Satellite analyzer was used to perform PT (Prothrombin Time) testing; (2) On 02/02/2021 the surveyor reviewed the implementation records for the current lot number of PT reagent and identified the following: (a) STA-Neoplastine CI PLUS lot# 256761 had been put into use on 01/01/2021; (b) The laboratory had verified a normal reference range of 12.0-14.3 seconds. (3) The surveyor then reviewed a patient PT report with testing performed on 01/07/2021. The reference range on the patient report was 11.4-14.4 seconds; (4) The surveyor reviewed the findings with the QA specialist who stated on 02/03/2021 at 11:10 am, the normal reference range that had been verified by the laboratory for PT was not included on the patient report.